UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** *Gaston Roberts et al. v. Zhejiang Huahai Pharmaceutical Co., et al.*, Case No. 1:20-cv-00946-RBK-JS	MDL No. 2875 Honorable Renée Marie Bumb District Court Judge

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF DR. JOHN RUSSO

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INTRODUCTION

Plaintiff seeks to have Dr. John Russo—an internal medicine doctor who happened to prescribe valsartan to his patients—offer various opinions on legal, regulatory, and labeling matters. In particular, Dr. Russo seeks to testify that:

- ZHP "failed to adequately warn physicians and patients of the risks of ZHP's contaminated Valsartan" (Russo Rep. at 10, Mar. 10, 2025 (Ex. 1 to Decl. of Nina Rose ("Rose Decl.")));
- ZHP's valsartan label and package inserts contained "affirmatively misleading representation[s] to physicians and patients[]" (*id.* at 11);
- No "reasonable physician" would have prescribed valsartan if ZHP warned of the risks of NDMA contamination (*id.* at 10-11);
- "[T]he contamination of ZHP's Valsartan exceeded" "the acceptable limits [of NDMA contamination] established by the FDA" (*id.* at 10); and
- The FDA's pronouncements that patients should continue taking valsartan while awaiting substitute medicines were "not an endorsement of the safety of" valsartan (*id.* at 11).

These opinions should be excluded for multiple reasons.

First, Dr. Russo's report and deposition are replete with impermissible legal opinions, including that ZHP "failed to warn" of the risks of valsartan contaminated with NDMA. Such opinions improperly invade the province of jurors by seeking to tell them that Plaintiff has satisfied an essential element of her claims.

Second, Dr. Russo's conclusions about the potential effect of different labeling or warnings on other physicians is inadmissible because Dr. Russo has no experience that renders him an "expert" on these issues, and even if he did, they are

entirely speculative and untethered to any objective methodology.

Third, Dr. Russo's opinions regarding FDA regulations, pronouncements and decisions should be excluded because he is not qualified to offer them, and the opinions lack any reliable basis. Moreover, to the extent Dr. Russo parrots other MDL plaintiffs' experts for select regulatory opinions, he did nothing to validate those opinions, which further warrants their exclusion.

Fourth, Dr. Russo's subjective opinion that ZHP acted unethically is not grounded in any expertise, would not assist the fact finder and is unduly prejudicial and confusing.

Lastly, Dr. Russo seeks to offer subjective narrative summaries of straightforward documents and deposition transcripts in the guise of expert testimony. Such recitations of record evidence do not qualify as expert testimony because jurors are equipped to review the evidence and interpret it for themselves.

For all of these reasons, discussed further below, the Court should exclude Dr. Russo's "expert" opinions.

BACKGROUND

Dr. Russo is an internal medicine physician (Russo Rep. at 1) who attended medical school in Mexico because he was not accepted into any school in the United States (Dep. of John A. Russo ("Russo Dep.") 59:7-13, May 13, 2025 (Rose Decl. Ex. 2)) and twice failed board exams (in internal medicine and pediatric medicine)

(*id.* 58:21-59:3). Beyond his own personal experience in prescribing valsartan to his patients, Dr. Russo conceded that he has no unique knowledge or expertise relevant to nitrosamines generally (*id.* 77:5-13); ZHP (*id.* 152:15-18); the potential risk of cancer associated with valsartan use (*id.* 216:8-217:21); or Mr. Roberts' case (*id.* 93:23-94:17 (Dr. Russo testifying that he does not "know those details" of Mr. Roberts' valsartan prescription or HCC cancer diagnosis)). Dr. Russo further conceded that he is not "an expert on the adequacy of labels" (*id*. 92:18-22; *id.* 107:18 ("I don't do labeling")); "[n]ot an expert on how marketing impacts physicians" (*id.* 91:25-92:12); and "not an expert in regulations" (*id.* 78:3-11; *id.* 78:16-17, 78:20-22; 79:4-23).

Despite his highly limited expertise and knowledge regarding the issues in this case, Dr. Russo seeks to provide a number of improper expert opinions, including legal conclusions regarding elements of Plaintiff's failure-to-warn claims (*e.g.*, Russo Rep. at 10 (ZHP "failed to adequately warn physicians and patients of the risks of ZHP's contaminated Valsartan")); speculative opinions regarding what a "reasonable physician" would do in the face of different warnings (*e.g.*, *id*. at 10-11 (no "reasonable physician" would have prescribed valsartan if ZHP warned of the risks of NDMA contamination)); statements regarding the beliefs of the FDA (*id.* at 11 (the FDA's pronouncements that patients should continue taking valsartan while awaiting substitute medicines were "not an endorsement of the safety of"

valsartan)); musings regarding the ethical responsibilities of product manufacturers like ZHP (*e.g.*, Russo Dep. 151:17-19 ("it was the responsibility of . . . these ZHP people to assure that [nitrosamines were] not present")); and bare recitations of other factual and documentary evidence (*e.g.*, Russo Rep. at 7 (quoting "excerpts of depositions of ZHP employees")).

Dr. Russo's methodology for reaching all of these opinions did not involve any sort of objective standard or analysis. (*See, e.g.*, Russo Dep. 92:13-17 (Dr. Russo did not "conduct any objective analyses like surveys to assess the impact or outcomes from marketing related to Valsartan products on physicians in this case"); *see also id.* 235:4-8.) Instead, he claims to have drawn from his own personal experiences as a practicing physician. (*Id.* 243:22-244:14 (Dr. Russo describing his methodology as "using my experience and my expertise as my role in the clinical setting of . . . patients that are being evaluated"); *id.* 109:22-110:5; 232:21-233:11 (similar).) Dr. Russo also purported to "look[] at the narrative of the events that took place" and a narrow set of documents, including "announcements" and "depositions," to "arriv[e] at [his] opinions." (*Id.* 243:22-244:14; *see also, e.g.*, Russo Rep. at 7 ("I have been provided excerpts of depositions of ZHP employees[.]").) But Dr. Russo's document review was selective and the documents were hand-picked by Plaintiff's counsel. (Russo Dep. 46:10-47:18 (Dr. Russo explaining he was supplied reference materials by Plaintiff's counsel and never

asked for additional materials).)

For example, although he includes an excerpt from Min Lee's deposition in his report (Russo Rep. at 7), Dr. Russo failed to review Min Lee's deposition testimony in its entirety (Russo Dep. 149:11-150:25). Nor did he review the exhibits that accompanied most of the depositions he reviewed. (Russo Dep. 48:18-49:18.) He also did not review any deposition of any case-specific fact witness other than Dr. Robichaux (*id.* 55:3-6), did not review any peer-reviewed articles (*id.* 54:25-55:2) and did not review any of Mr. Roberts' medical records (*id.* 54:22-24).

ARGUMENT

Under recently amended Fed. R. Evid. 702, Plaintiff has the burden of "demonstrat[ing] to the court that it is more likely than not" that her expert is sufficiently qualified to offer his proposed testimony; that the expert's opinions are "based on sufficient facts or data"; that the opinions are the "product of reliable principles and methods"; and that they reflect a "reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702. As this Court recently recognized, the recent amendments were "'made necessary by the courts that have failed to apply correctly the reliability requirements of'" Rule 702. *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. MDL 19-2875 (RMB/SAK), 2025 WL 1024048, at *14 (D.N.J. Apr. 7, 2025) (citation omitted) (Bumb, J.) (citing Fed. R. Evid. 702, advisory committee's note to 2023 amendments). In addition, "[t]he

Third Circuit has also recently reemphasized the district court's 'rigorous gatekeeping function.'" *Id.* at *14 (citing *Cohen v. Cohen*, 125 F.4th 454, 460-61, 463 (3d Cir. 2025)).[1] The Court should exclude Dr. Russo's opinions in their entirety under this standard for multiple reasons.

I. DR. RUSSO SHOULD NOT BE ALLOWED TO OFFER LEGAL OPINIONS.

Dr. Russo's expert report is rife with legal conclusions, including an opinion that ZHP "failed to warn" of the risks of Valsartan contaminated with NDMA.

The "prohibition on experts testifying as to their own legal conclusions is 'so well established that it is often deemed a basic premise or assumption of evidence law'" that has been adopted by "every circuit." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 472 (D.N.J. 2008) (citations omitted) (striking expert

[1] *See also, e.g., In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 348 n.7 (6th Cir. 2024) ("Rule 702's recent amendments . . . were drafted to correct some court decisions incorrectly holding 'that the critical questions of the sufficiency of an expert's basis . . . are questions of weight and not admissibility.'") (citation omitted); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283-84 (4th Cir. 2021) (amendments to Rule 702 were adopted "to address this 'pervasive problem'" of "holding" that an expert's reliance on insufficient data and misapplication of principles and methods "were ones of weight for the jury") (citation omitted); *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, 707 F. Supp. 3d 309, 334-35 & n.27 (S.D.N.Y. 2023) ("[O]ne purpose of the amendment was to emphasize that '[j]udicial gatekeeping is essential . . . .'") (citation omitted); *Optical Sols., Inc. v. Nanometrics, Inc.*, No. 18-cv-00417-BLF, 2023 U.S. Dist. LEXIS 208824, at *4-5 (N.D. Cal. Nov. 21, 2023) (expert evidence did not satisfy prior version of Rule 702, "let alone . . . the more stringent standard under the amendment to Rule 702").

report that was "replete with legal conclusions and speculations that ultimately render his entire report deficient"). As the Third Circuit has explained, such opinions are improper because they "interfere with the district court's 'pivotal role in explaining the law to the jury'" and effectively predetermine how that law should be applied to the facts of the case. *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013) (affirming exclusion of "testimony . . . opin[ing] on the reasonableness of Deputy Moorman's actions," which essentially told jurors that police officer acted excessively in civil rights lawsuit) (citation omitted).[2]

Consistent with this authority, courts have repeatedly prohibited experts from opining that a defendant "failed to warn" because such testimony "usurp[s] the jury's fact-finding function" on a key element of the plaintiff's claims. *See, e.g.*, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL

[2] *See also, e.g.*, *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 218 (3d Cir. 2006) (expert may not testify "as to what was required under the law, or whether the defendant complied with the [law]"); *United States ex rel. Silver v. Omnicare, Inc.*, No. 1:11-cv-01326-NLH-AMD, 2023 WL 2808098, at *8-13 (D.N.J. Mar. 31, 2023) (excluding expert opinions that improperly explained "what the [Anti-Kickback Statute] prohibits," "venture[d] toward applying [defendant's] actual alleged actions to its identified legal duties," indicated that the facts "suggest" defendant "violated the [statute]," as well as portions of an expert report that "state[d] what is and is not a violation of the" statute); *Crockett v. Luitpold Pharms., Inc.*, No. 19-276, 2023 WL 2187641, at *3 (E.D. Pa. Feb. 23, 2023) (excluding expert testimony that labeling laws were "improperly followed" or that "failures to update the labeling, rendering it false & misleading . . . meets the definition of the regulatory term 'misbranded'") (citation omitted).

4215639, at *2 (S.D. W. Va. Sept. 4, 2018) (excluding expert testimony that defendant "'failed to warn' physicians and provided inadequate instructions"); *Redding v. Coloplast Corp.*, No. 6:19-CV-1857-ORL-41GJK, 2020 WL 13882977, at *8 (M.D. Fla. Nov. 30, 2020) (prohibiting an expert from testifying "that [d]efendant 'failed to warn' about the risks" because such testimony "would be impermissible legal conclusions"); *Arevalo v. Coloplast Corp.*, No. 3:19CV3577-TKW-MJF, 2020 WL 3958505, at *20 (N.D. Fla. July 7, 2020) (expert opinion "that [d]efendant 'failed to warn' patients and physicians of their alleged risks constitutes impermissible legal conclusions or uses legal terms of art"), *aff'd sub nom. Arevalo v. Mentor Worldwide LLC*, No. 21-11768, 2022 WL 16753646 (11th Cir. Nov. 8, 2022).

Dr. Russo's "opinions" contravene this fundamental prohibition. Dr. Russo states that he was retained to opine on whether ZHP "adequately warned physicians and patients of the risks of using ZHP's Valsartan products contaminated with nitrosamines including NDMA." (Russo Rep. at 1; *id.* at 2 (opining "that ZHP and its subsidiaries failed to adequately warn physicians and patients of the risks of the nitrosamine-contaminated Valsartan").) Dr. Russo concludes that ZHP's "failure . . . to make any disclosure of the NDMA contamination rendered the warnings for the contaminated Valsartan inadequate by definition" (Russo Rep. at 5)—i.e., that ZHP failed to warn ***as a matter of law***. (*See also id.* at 6 ("Based on the complete

lack of disclosure, no physician or patient would have had any reason to know or suspect that ZHP's Valsartan was contaminated with NDMA at any time before public disclosure occurred in 2018."); *id.* at 10 (opining that ZHP "failed to disclose the NDMA contamination to the FDA, and failed to adequately warn physicians and patients of the risks of ZHP's contaminated Valsartan").)

Because it is the function of the Court to instruct the jury on the applicable law and because "[i]t is the jury's job to determine whether [defendant's] conduct violated the [law] . . . not the expert's," *Allscripts Healthcare, LLC v. Andor Health, LLC*, No. 21-704-MAK, 2022 WL 3021560, at *27 (D. Del. July 29, 2022), Dr. Russo's legal opinions should be excluded under Rule 702.

II. DR. RUSSO'S WARNING CAUSATION OPINIONS ARE IMPROPER.

Dr. Russo also seeks to testify on how a "reasonable physician" would respond to ZHP's warnings, reaching the conclusion that no "reasonable physician" would have prescribed valsartan if ZHP warned of the risks of NDMA contamination. (Russo Rep. at 10-11.) But Dr. Russo has no experience that renders him an "expert" on these issues, and even if he did, such testimony is entirely speculative and not grounded in any hard evidence.

First, Dr. Russo is not qualified to opine on valsartan's labeling or warnings, much less how a "reasonable physician" would react to such warnings.

As this Court has explained, "the witness must be qualified to testify as an

expert, which requires 'that the witness possess specialized expertise.'" *In re Valsartan*, 2025 WL 1024048, at *10 (citation omitted). Courts have made clear that "[s]imply being a doctor who is the intended audience of the[drug] labels does not make [someone] qualified to opine on the adequacy of the labels." *McWilliams v. Novartis AG*, No. 2:17-CV-14302-ROSENBURG/MAYNARD, 2018 WL 3369065, at *1, *3 (S.D. Fla. July 9, 2018) (excluding oncologist/hematologist from opining that the drug label did not effectively warn physicians of the drug's association with atherosclerotic-related conditions); *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 U.S. Dist. LEXIS 9037, at *36 (E.D. Pa. June 20, 2010) (experiences as medical doctors "do not qualify them to opine as experts about what all doctors generally consider in making prescription decisions"); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 556-57 (S.D.N.Y. 2004) (expert was "not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information").

Dr. Russo—an internal medicine doctor—bases his opinions solely on his own anecdotal experience "treat[ing] patients for high blood pressure" and prescribing medications, including valsartan. (Russo Rep. at 2; *id.* at 4 (stating that he relies on his "training and clinical experience" as a prescribing physician "[i]n evaluating the question of the adequacy of the warnings for the sale of Valsartan contaminated with NDMA"); Russo Dep. 243:7-21 (Dr. Russo describing his

expertise in labeling as "understanding all of the information that is important to properly assess a patient").) But Dr. Russo conceded that he is not "an expert on the adequacy of labels" (Russo Dep. 92:18-22) and has no experience in drafting, formulating or interpreting drug warnings (*id.* 107:18; 78:23-25). He similarly agreed that he is "[n]ot an expert on how marketing impacts physicians." (*Id.* 91:25-92:12.)

Dr. Russo's inability to answer basic questions at his deposition regarding drug labels and warnings further "demonstrates [that he] lacks competency to assist the jury in understanding" these issues. *See Dreyer v. Ryder Auto. Carrier Grp., Inc.*, 367 F. Supp. 2d 413, 428 (W.D.N.Y. 2005) ("Proctor's inability to explain, within the relatively flexible confines of a pretrial deposition of a proposed expert witness, how the good engineering practices referred to by Proctor would be applied" to the facts of the case "demonstrates Proctor lacks competency to assist the jury in understanding the issues."). Although Dr. Russo wrote in his report that disclosure of certain risks "could have been done in the labeling, the package insert, and/or a Dear Doctor letter, at the very least" (Russo Rep. at 5; *id.* at 10 (opining risks "had to be disclosed, whether via the label, the package insert, a Dear Doctor letter, or otherwise, to enable reasonable physicians and patients to make informed decisions")), Dr. Russo testified that he has no knowledge of how information pertaining to risks are disseminated to "patients . . . or pharmacists." (Russo Dep.

101:24-102:9 (Dr. Russo testifying that his "understanding is the FDA disseminates information" but he did not "know the exact [FDA] policies that would have forbid ZHP to directly send [warnings] to patients"); *id.* 131:25-132:1, 132:19-133:20 (Dr. Russo testifying that he did not know "what form has to be filled out" with the FDA for ZHP to change the valsartan label)). In short, Dr. Russo's status as "a doctor" who reads labels does not "qualif[y him] to opine on the adequacy of the labels." *McWilliams*, 2018 WL 3369065, at *1, *3.

Second, Dr. Russo's opinions regarding how a "reasonable physician" would react to labeling and/or marketing or warnings are entirely speculative and not grounded in any hard evidence.

"[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Accordingly, the Third Circuit has long held that an expert who has "employed absolutely no methodology at all" cannot offer reliable testimony at trial. *See Scrofani v. Stihl Inc.*, 44 F. App'x 559, 561-62 (3d Cir. 2002) (affirming exclusion of expert who "employed absolutely no methodology at all," merely setting forth "a series of unsubstantiated opinions") (citation omitted). That principle is all the more clear in light of the recent amendments to Rule 702. *See In re Valsartan*, 2025 WL 1024048, at *18-19 ("[T]estimony that . . . an adulterated drug can never have any

value whatsoever is nothing more than an *ipse dixit* assertion of worthlessness."); *see also Cohen*, 125 F.4th at 463 (affirming exclusion of expert who "did not elaborate on the 'research' underpinning his conclusory statement").

In accordance with this principle, expert testimony about the impact of marketing or warnings on prescribing doctors must be grounded in "reliable evidence." *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 277 (D.N.J. 2006) (excluding physician's "testimony regarding what physicians in general think/know and how they make prescription decisions" because such testimony is "speculative and not based on reliable evidence"); *Advanced Med. Optics, Inc. v. Alcon, Inc.*, No. CIV.A. 03-1095-KAJ, 2005 WL 782809, at *3 (D. Del. Apr. 7, 2005) (precluding doctor from opining on "the general preferences of other surgeons" on the basis that such testimony was "speculative and not supported by reliable data").

Dr. Russo seeks to testify "as to how ***all*** physicians would react to news of potential low level contamination of Valsartan with NDMA" based solely on his "experience and understand[ing of] what the standard of care is for practicing physicians." (Russo Dep. 232:21-233:11 (emphasis added).) But Dr. Russo's supposed "experience and understanding" speak, at most, to his qualifications, not to the reliability of his opinions, and the two are "distinct concepts" that "courts must take care not to conflate[.]" *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir.

2004); *see also Cohen*, 125 F.4th at 460. Indeed, Dr. Russo expressly conceded that he did not "conduct any objective analyses like surveys to assess the impact or outcomes from marketing related to Valsartan products on physicians in this case[.]" (Russo Dep. 92:13-17.)[3] Without any citation to objective "reliable evidence," Dr. Russo's "testimony regarding what physicians in general think/know" and how they would respond to different labeling is speculative and inadmissible. *Pfizer Inc.*, 461 F. Supp. 2d at 277; *see also In re Valsartan*, 2025 WL 1024048, at *19 (excluding expert's testimony on the basis it "[wa]s unreliable in light of its inconsistencies and the stark lack of scientific or economic basis for her methodology").

III. DR. RUSSO LACKS A RELIABLE BASIS FOR HIS REGULATORY OPINIONS.

Dr. Russo also seeks to testify about FDA regulations and decisions, variously opining about "several [] public notifications [issued by the FDA] regarding the contamination and recall" (Russo Rep. at 8-9); that "the contamination of ZHP's Valsartan exceeded" "the acceptable limits [of NDMA contamination] established by the FDA" (*id.* at 10); and that "[t]he FDA announcement that informed patients not to cease use of the contaminated Valsartan until they could consult their

[3] Dr. Russo's repeated reference to "reasonable physicians in clinical practice" (*e.g.*, Russo Dep. 252:10-16) does not salvage his opinion either because Dr. Russo has not undertaken any methodologically sound analysis to determine what a "reasonable physician" would believe or do; rather, he is pontificating about what ***he personally*** would believe or do. And because Dr. Russo never treated Mr. Roberts, his personal beliefs are entirely irrelevant to this litigation.

physician . . . was not an endorsement of the safety of the drugs at issue despite the presence of the NDMA" (*id.* at 11). Dr. Russo's opinions regarding FDA regulations, pronouncements and decisions should be excluded because he is not qualified to offer them, and they lack any reliable basis.

First, Dr. Russo plainly does not have any qualifications that render him an expert on FDA regulations and decisions.

Courts have repeatedly held that medical doctors without specialized FDA experience should not be permitted to opine about regulatory matters because they are not experts on FDA regulations and labeling. *See, e.g.*, *In re Diet Drugs*, 2000 U.S. Dist. LEXIS 9037, at *36 (experience as medical doctors "does not qualify them to speak as experts in the field of the requirements of the federal regulations regarding labeling and warnings for FDA approved drugs"); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL No. 1203, 2001 WL 454586, at *20 (E.D. Pa. Feb. 1, 2001) (finding that "testimony about whether [] labels met regulatory standards is beyond the expertise of" a cardiologist and a pediatric cardiologist because "[n]either witness has anything more than incidental experience with FDA regulations addressing the approval process for labeling"); *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *9 (D. Ariz. Nov. 20, 2012) (granting motion to exclude "any testimony from Dr. Busfield about FDA regulations" where "Dr. Busfield [wa]s qualified to

opine on medical issues, but . . . his expertise d[id] not encompass the FDA regulatory history of pain pumps"); *In re Trasylol Prods. Liab. Litig.*, MDL No. 1928, 2011 WL 7109297, at *5-6 (S.D. Fla. Apr. 27, 2011) (excluding Canadian physician's opinion on FDA labeling requirements because "he is not an expert in FDA regulations" or labeling, and testimony on what physicians in general think would be speculative); *Bouchard v. Am. Home Prods. Corp.*, No. 3:98 CV 7541, 2002 WL 32597992, at *5 (N.D. Ohio May 24, 2002) ("Without a solid underpinning in FDA regulations, Dr. Busch appears ill-equipped to offer expert testimony concerning the sufficiency of information used to comply with those regulations.").

Dr. Russo admittedly is "not an expert in regulations"; instead, he is merely "a clinician that gathered information from regulatory sources." (Russo Dep. 78:3-11.) Dr. Russo never worked at the FDA (or any public health regulatory body) (*id.* 78:16-17, 78:20-22); never consulted or advised about the language used on drug warnings (*id.* 78:23-79:6); and never provided guidance to the FDA and has never been involved in FDA decision-making (*id.* 75:12-18, 80:19-21). As a result, Dr. Russo could not answer basic questions regarding "regulatory requirements"; "did not focus" on and could not "remember . . . specific details of regulatory requirements"; and testified that he would "leave that to other experts in this case." (*Id.* 105:16-106:3; *see also id.* 101:24-102:9 (Dr. Russo testifying that he did not

"know the exact [FDA] policies that would have forbid ZHP to directly send [warnings] to patients").) In short, Dr. Russo is plainly "ill-equipped to offer expert testimony concerning the sufficiency of information used to comply with [FDA] regulations." *Bouchard*, 2002 WL 32597992, at *5.

Second, Dr. Russo's regulatory opinions should also be excluded because they lack any reliable foundation. An expert's testimony on the application of regulatory requirements to a defendant's purported conduct is limited to opinions based on "objective standards" rather than "personal views." *Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 U.S. Dist. LEXIS 44507, at *8-9 (D. Ariz. Mar. 29, 2012) (expert "must provide some analysis, opinion, or expertise when testifying about the regulatory process and history of pain pumps"). Thus, regulatory opinions "devoid of regulatory analysis" are speculative and inadmissible. *Hines v. Wyeth*, No. 2:04-0690, 2011 U.S. Dist. LEXIS 74011, at *17-20 (S.D. W. Va. July 8, 2011) (excluding regulatory opinions where expert "fails to cite a single rule or regulation that would require defendants to act as she suggests they should have") (citation omitted); *see also In re Valsartan*, 2025 WL 1024048, at *19 ("Conti's opinion is largely argument and advocacy based on her own *ipse dixit*, rather than a reliable application of economic principles and methods to the facts of the case.").

Dr. Russo's regulatory opinions are "devoid of regulatory analysis." For example, Dr. Russo seeks to opine—without citation to any authority—that

"[t]he FDA announcement that informed patients not to cease use of the contaminated Valsartan until they could consult their physician . . . was not an endorsement of the safety of the drugs at issue despite the presence of the NDMA." (Russo Rep. at 11; *see also id.* at 8 ("The FDA made the reasonable determination that the immediate risk had to be prioritized . . . .").) Although Dr. Russo claims to know "what the FDA expects of safety," he does not support that claim with any empirical data; rather, he bases it solely on ***his*** conclusory assumption that "this is the expectation of any reasonable practicing clinical physician." (Russo Dep. 109:22-110-3; *see also id.* 131:3-7 (stating the FDA's "position is exactly what my position is, they're consistent -- they are concerned with the safety of patients. They want information to clearly be stated on warning labels.").) But "nothing in either *Daubert* or the Federal Rules of Evidence" permits the admission of expert testimony "that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.[4]

[4] Dr. Russo's speculation about what the FDA knew and the import of that agency's own pronouncements about valsartan separately violates the well-established principle that "the intent, motives or states of mind of [] regulatory agencies . . . have no basis in any relevant body of knowledge or expertise." *In re Rezulin*, 309 F. Supp. 2d at 546 (excluding expert opinions regarding, *inter alia*, "what the FDA might have done with different information"); *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1338 (S.D. Fla. 2010) (excluding expert testimony regarding FDA's alleged "concerns" and "'indications' that certain warnings would be insufficient" because "it improperly touches upon the FDA's knowledge and intent").

Nor can Dr. Russo evade the dictates of Rule 702 by "parrot[ing]" the regulatory opinions of other experts in this MDL. *See Leese v. Lockheed Martin Corp.*, 6 F. Supp. 3d 546, 553 (D.N.J. 2014) (holding an expert "may not parrot or act as a mouthpiece for other experts' opinions, without independent verification of those opinions" because Rule 702 "contemplates that a testifying expert can validate the facts, data and opinions he relied upon . . . and be subject to cross-examination on them"). For example, although Dr. Russo relies on Dr. Hecht in offering his "risk-benefit analysis" of valsartan contaminated with NDMA and asserting that "the contamination of ZHP's [v]alsartan exceeded" "the acceptable limits established by the FDA" (Russo Rep. at 10), Dr. Russo made clear that he failed to "perform an independent [review] of the information that [Dr. Hecht] was providing in his report." (Russo Dep. 267:15-19.) Such "unblinking reliance" on another expert's opinions renders Dr. Russo's opinions inadmissible under Rule 702. *See In re TMI Litig.*, 193 F.3d 613, 715-16 (3d Cir. 1999) (affirming exclusion of expert where expert's "failure to assess the validity of the opinions of the experts he relied upon . . . demonstrate[d] that the methodology he used to formulate his opinion was flawed under *Daubert*").[5] For this reason, too, Dr. Russo's regulatory opinions are not based

[5] Dr. Russo also relies on the reports of experts Hecht and Plunkett to provide a summary of valsartan's alleged NDMA contamination. (*See* Russo Rep. at 5.) But as with his supposed "risk-benefit analysis," he made no independent verification of the contents of either expert's report, and he concededly lacks expertise in NDMA

on a reliable methodology.

IV. DR. RUSSO'S OPINIONS CONCERNING ZHP'S ETHICAL RESPONSIBILITES SHOULD BE EXCLUDED.

Dr. Russo's proposed testimony also includes commentary on Defendants' ethics, which is not a proper subject of expert testimony, is irrelevant, and is unfairly prejudicial and confusing.

Testimony "concerning the ethical obligations of . . . companies and whether the defendants' conduct was ethical [is] inadmissible" because it rests on "personal, subjective views" rather than "knowledge" within the meaning of Rule 702. *In re Rezulin*, 309 F. Supp. 2d at 542-43; *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1053, 1057-58 (D. Minn. 2007) (excluding expert testimony that "Bayer was unethical" because "[p]ersonal views on corporate ethics and morality are not expert opinions"). Indeed, courts in this circuit have made clear that "subjective views of ethics [even if] informed by well-known principles does not convert them into objective, reliable, scientific knowledge." *See Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 WL 1673805, at *8-9 (E.D. Pa. May 4, 2011) (holding expert testimony that defendant had a "'responsibility' to develop a better warning . . . and better communicate the risks of their product are not based on reliable methodology").

Dr. Russo offers impermissible subjective testimony regarding the ethical

(Russo Dep. 77:5-13), rendering this aspect of his report doubly inadmissible.

appropriateness of ZHP's actions. For example, Dr. Russo accuses ZHP of withholding "material information with regard to a 'potential safety hazard'" and believes that "the unreasonable safety risk [] should have been disclosed to physicians and patients." (Russo Rep. at 10.) He also asserts that it is the "responsibility of th[e] drug company" to ensure "the safety of the production of that . . . drug." (Russo Dep. 106:1-14; *see also id.* 102:2-17 (Dr. Russo testifying that "as soon as they learned of this, because of this tremendous danger that was posed, they would -- they would certainly be obligated to contact the FDA or other national organizations to assure safety of patients"); *id.* 151:9-20 ("it was the responsibility of . . . these ZHP people to assure that [nitrosamines were] not present").) Because Dr. Russo does not reference (much less reliably apply) any objective standard in offering these claims, they are nothing more than "subjective views" rather than "objective, reliable, scientific" evidence. *Wolfe*, 2011 WL 1673805, at *8-9.

Even assuming these ethics opinions were the product of reliable methods, they "would not assist the [jury] in determining any factual dispute in this case," which will turn on whether the valsartan Mr. Roberts took was defective, whether it caused his specific cancer, and what ZHP knew about the possibility of NDMA in the medication and when. *See In re Rezulin*, 309 F. Supp. 2d at 544 ("While the defendants may be liable in the court of public opinion, or before a divine authority

for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits."); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-cv-17000, 2005 WL 1868046, at *20-21 (N.D. Ohio Aug. 8, 2005) (excluding "ethics testimony" because the "critical question for the jury in this case is whether the defendant corporations did what the law required them to do, not whether, from a societal perspective, they did what an 'ethical corporation' should have done") (emphasis omitted). Moreover, any tenuous probative value of Dr. Russo's testimony would be "vastly outweighed by the tendency of such testimony to encourage the jury to impose liability on an improper basis" and such testimony is also inadmissible under Rule 403. *Wolfe*, 2011 WL 1673805, at *9 (expert's testimony about defendant's "social responsibility and ethical obligations" was alternatively inadmissible under Rule 403). These opinions boil down to accusations that Defendants engaged in wrongful and immoral conduct—with no citation or reference as to what the standard of conduct actually is for a product manufacturer. Such incendiary claims bearing the imprimatur of an "expert" would be highly prejudicial and confusing, further confirming that Dr. Russo's opinions on this subject are inadmissible.

V. DR. RUSSO'S REPORT CONTAINS IMPROPER SUMMARIES OF EVIDENCE.

Finally, Dr. Russo's mere recitation of various pieces of evidence under the guise of expert testimony is also plainly improper.

An expert may not "simply rehash internal corporate documents" because such "opinions are not properly the subject of expert testimony[.]" *O'Bryant v. Johnson & Johnson*, No. 20-2361 (MAS) (DEA), 2022 WL 7670296, at *13 (D.N.J. Oct. 13, 2022) (Shipp, J.) (testimony that "simply parrot[s] [d]efendant's corporate documents or offer[s] a narrative account of events from them will not be helpful to the jury") (citation omitted). Nor may an expert "simply summarize the facts and the depositions of others." *Crowley v. Chait*, 322 F. Supp. 2d 530, 553 (D.N.J. 2004) ("[N]either [the expert] nor any other witness will be permitted to simply summarize the facts and the depositions of others."); *see also Modica v. Maple Meadows Homeowners Ass'n*, No. 13-0036, 2014 WL 1663150, at *1 n.3 (E.D. Pa. Apr. 2, 2014) (excluding expert testimony that merely "summarizes deposition testimony"); *Kia v. Imaging Scis. Int'l, Inc.*, No. 08-5611, 2010 WL 3431745, at *5 (E.D. Pa. Aug. 30, 2010) ("[A] party may not 'filter fact evidence and testimony through his expert merely to lend credence to the same' nor may expert testimony be used merely to repeat or summarize what the jury independently has the ability to understand."). As one court succinctly put it, "simply summariz[ing] a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008), *aff'd in part, rev'd in part*, 586 F.3d 547 (8th Cir. 2009).

Dr. Russo's report contravenes these principles by simply parroting or quoting

from evidence (that jurors are fully capable of reading for themselves). For example:

- Dr. Russo's expert report includes a number of "excerpts of depositions of ZHP employees," including Min Li, Eric Gu, and Hai Wang. (Russo Rep. at 7.)
- Dr. Russo seeks to synthesize select deposition testimony from Mr. Roberts' cardiologist, Dr. Robichaux, claiming that Dr. Robichaux "would not have prescribed contaminated Valsartan to Mr. Roberts . . . if he had known of the contamination[.]" (*Id.* at 10.)
- Dr. Russo purports to summarize select FDA announcements (*id*. at 8-9) and copies verbatim text from select FDA regulations (*see id.* at 4 (quoting 21 C.F.R. § 201.57(a)(10))).

Dr. Russo does not actually apply any expertise to these documents or incorporate them into any expert opinions. He simply summarizes them, which "will not be helpful to the jury." *O'Bryant*, 2022 WL 7670296, at *13.

Dr. Russo's regurgitation of record evidence is all the more improper because the documents and depositions he seeks to narrate to jurors were admittedly hand-picked by Plaintiff's counsel. (Russo Dep. 46:10-47:17 (Dr. Russo explaining he was supplied reference materials by Plaintiff's counsel and never asked for additional materials).) For example, although he includes excerpts from Min Lee's deposition in his report (Russo Rep. at 7), Dr. Russo failed to review Min Lee's deposition testimony in its entirety (Russo Dep. 149:11-150:25). And the only deposition testimony from Mr. Roberts' numerous treating physicians that Dr. Russo reviewed was from Dr. Robichaux. (*See* Russo Rep. Ex. B at 5.) As a result, Dr. Russo focuses on testimony by Dr. Robichaux that he would not have prescribed

valsartan if he had known there was NDMA in the product. (Russo Rep. at 10.) But Dr. Russo ignores contradictory testimony from Mr. Roberts' other cardiologist, Dr. Ralph Buckley, who worked at the same practice with Dr. Robichaux and testified that many drugs have risks and he defers to the FDA, and whether it has approved a medication, in deciding whether to prescribe it. (Dep. of Ralph Buckley 84:22-85:1, Feb. 7, 2025 (Rose Decl. Ex. 3); *id.* 86:12-87:11 (Dr. Buckley "rel[ies] on the FDA to help me with all those issues [regarding contamination]"); *id.* 87:12-22 (Dr. Buckley testifying that "there are a lot of side effects on different medicines that I prescribe that I worry about. But [] I rely on the FDA to help me decide").)

For this reason, too, the Court should grant Defendants' motion to exclude the testimony of Dr. Russo. *See Crowley*, 322 F. Supp. 2d at 542 (excluding expert's opinion based on "information spoonfed to him by plaintiff's counsel"; "The information upon which an expert bases his testimony must be reliable, and the selective furnishing of information by counsel to an expert runs afoul of Fed. R. Evid. 703, which, in addition to Rule 702, must be considered by a court for *Daubert* purposes."); *Repa v. Napierkowski*, No. 1:19-CV-00101-RAL, 2022 WL 1522360, at *3 (W.D. Pa. May 13, 2022) (excluding expert's "'opinions'" that "summarize witness testimony" because "selective summary of party and witness testimony and other evidence [in an expert report] will not assist the jury").

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. John Russo's opinions.

Dated: May 22, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 22, 2025, a true and correct copy of the foregoing document was served upon counsel of record via operation of the Court's electronic filing system.

Dated: May 22, 2025

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